

**REMARKS**

Claims 1-3, 7, 18, 20 and 23 were rejected under 35 U.S.C. §102(b) as being anticipated by US Pat. 5,916,244 (Walters). Amended Claim 1 describes an electrode comprising an electrode body having a first and second side, wherein the first side comprises a flexible moisture barrier layer comprising a heat-sealable material and the second side comprises a conductive layer; an electrically conductive gel layer disposed on the electrode body and which is further in electrical communication with the conductive layer, the periphery of the heat-sealable moisture barrier layer extending beyond the periphery of the gel layer; and a rigid release liner heat-sealed to said flexible barrier layer around the periphery of said gel layer. As is well known, medical electrodes are coated with a conductive gel which performs two functions. The gel is electrically conductive to conduct electrical signals of the body to a conductor of the electrode. The gel is also sticky or tacky which enables the electrode to be adhered to the body during use by the gel. But gels are hydrophilic and can desiccate or dry out with exposure to air. If the gel dries out, a stored electrode will not be usable at the moment it is needed. To prevent gel desiccation, electrodes historically have been enclosed in sealed in moisture-impermeable bags or pouches, as exemplified by the pouches 60, 212 shown in the cited Olson et al. patent. But the pouches can be difficult to open, require proper disposal, and prevent the electrode leads from being preconnected to a defibrillator. When the electrodes are preconnected to a defibrillator, the defibrillator can test them occasionally to make sure that the gel has not dried out. To avoid the need for a bag or pouch and leave the leads free for connection to a defibrillator, some have tried covering the gel with a moisture-impermeable cover such as the release liner 44 shown in the Walters patent. A better approach along these lines is to seal the periphery of the cover around the gel as shown by releasing layer 40 in US Pat. 6,272,385 (Bishay et al.) Just before use the cover is peeled off of the gel and the electrode is ready to use.

However, the present inventors have found that it is difficult to peel the cover off of the electrode. The electrode is flexible, which makes it difficult to peel away the cover. Furthermore, the peeled covers can be a distraction at the site of a rescue when a first responder is trying to resuscitate a victim of cardiac arrest. The present invention addresses these shortcomings by employing a rigid release liner. It has been found that, rather than peel a cover off of the electrode, it is easier to peel an electrode off of a rigid release liner. When the electrodes are removed only a rigid card remains, which is less distracting than

peeled covers. The electrode of Claim 1 includes a further feature, which is the use of heat sealing to seal the electrode to its rigid release liner. Heat sealing is quick and easy, and avoids the need for adhesives which can contaminate the electrode and its gel.

Walters, as discussed, simply covers his gel with a transparent release liner, and the tacky gel holds it in place. There is no indication that Walters' release liner 44 is rigid. It appears to be removed by peeling off the release liner. Furthermore, the release liner 44 only covers the gel, it does not enclose it and seal the gel from desiccation. The air around the sides of the release liner can dry out the gel, starting from its periphery. The release liner 44 is not heat-sealed over the gel as recited in Claim 1. In fact, it is not peripherally sealed at all. It is just a cover. For all of these reasons it is respectfully submitted that Claim 1 and its dependent claims are patentable over Walters.

Amended Claim 18 describes a self-storing electrode system comprising first and second electrode bodies each having a first and second side, wherein the first side comprises a flexible moisture barrier layer having a heat-sealable periphery and the second side comprises a conductive layer which does not extend to the periphery of the moisture barrier layer; an electrically conductive gel disposed on each of the electrode bodies which is in electrical communication with the conductive layer of each electrode; a rigid release liner sealed by a heat seal to the periphery of the flexible moisture barrier layer to enclose, protect and prevent desiccation of the gel layer; and a lead wire electrically coupled to each electrode by means of a path that does not disrupt the moisture integrity of the release liner seal. Claim 18 calls for a flexible moisture barrier layer having a heat-sealable periphery, which is not shown or suggested by Walters. The periphery of Walters' release liner 44 is not sealed at all. Claim 18 calls for a rigid release liner, which is not found in Walters. Hence Walters does not have a rigid release liner peripherally sealed to a flexible moisture barrier layer to prevent desiccation of a gel layer as called for by Claim 18. For all of these reasons it is respectfully submitted that Claim 18 and its dependent claims are patentable over Walters.

Claims 4, 5, and 21 were rejected under 35 U.S.C. §103(a) as being unpatentable over Walters in view of US Pat. 4,989,607 (Keusch et al.) Keusch et al. is directed to hydrophilic gels and was cited for its mention of a fluoropolymer film for a flexible barrier layer in column 13, lines 46-49. However, this passage describes a pouch or envelope for an electrode which is made of aluminum foil polymer laminate. Nowhere is a fluoropolymer film mentioned in Keusch et al. However it is seen that Keusch et al. tell the reader in column 14, lines 35-42 to cover their gel with "a sheet of peelable release liner, e.g.,

polyethylene." This is the same approach as Walters, a peelable sheet which simply covers the gel. Thus, Keusch et al. adds nothing to Walters that would cause the combination of the two to render Claims 1 and 18, discussed above, unpatentable. It follows that the combination of Walters and Keusch et al. cannot render dependent Claims 4, 5, and 21 unpatentable.

Claim 6 and 19 were rejected under 35 U.S.C. §103(a) as being unpatentable over Walters in view of US Pat. 4,419,998 (Heath). Heath describes an electrode in his Fig. 4 which, when assembled, is sealed by a cover 83 which is attached with an adhesive 81 over a gel disk 75. Heath does not use a release liner, but uses a cover. Heath does not use heat sealing but uses an adhesive instead. Thus, Heath does not cure the deficiencies of Walters with regard to independent Claims 1 and 18. It follows that Claims 6 and 19, which depend from these independent claims, are patentable over Walters and Heath by reason of their dependency.

The Examiner also invokes Keusch et al. with regard to Claim 19. But the passage cited in Keusch et al. for heat-sealing a moisture barrier layer to a release liner does not relate to either of these elements. The cited passage calls for packaging a finished electrode in a heat sealed pouch or envelope. The release liner of Keusch et al. is described in the following column 14, a peelable sheet of polyethylene which is presumably placed on the gel before the electrode is placed in the pouch or envelope.

Claims 9-17 were rejected under 35 U.S.C. §103(a) as being unpatentable over Walters in view of Keusch et al. and further in view of US Pat. 5,817,151 (Olson et al.) Amended Claim 9 describes an electrode system comprising a pair of electrodes disposed on opposite sides of a rigid non-conductive release liner, wherein each electrode comprises an electrode body having first and second sides, wherein the first side comprises a flexible moisture barrier layer having a sealable periphery and the second side comprises a conductive layer, and an electrically conductive gel layer interposed between the conductive layer and the rigid non-conductive release liner, wherein the periphery of the moisture barrier layer of each electrode is sealed to the release liner to enclose the gel layer of each electrode in a moisture barrier enclosure on its respective side of the rigid release liner. The electrode system of Claim 1 uses one rigid release liner with an electrode peripherally sealed to either side. This seals the gel layer of each electrode in a moisture barrier enclosure on each side of the rigid release liner. As previously mentioned Walters and Keusch et al. do not show or suggest a rigid release liner, but cover sheets which are peeled off of the gel. The Walters and Keusch et al. cover sheets do not hermetically seal the gel against moisture loss,

they just cover it and allow air to dry out the gel from the edges. Keusch et al. prevents desiccation in the usual way by telling the reader in column 13 to put the electrode in a sealed pouch or envelope. Olson et al. do not have a rigid release liner either. They use a plastic sheet or treated paper 61, 206 to cover their gel. Their electrodes are then sealed in a package 60 to prevent desiccation. In column 2 Olson et al. refer to another application of theirs which is now enclosed US Pat. 5,645,571. In the '571 patent the electrodes 50 are stuck on either side of a flexible release liner 61, shown folded over in Fig. 5. The electrodes 50 are not sealed to release liner 61. For desiccation protection the electrodes are sealed in a package with their wires sticking out through the seal as shown in Fig. 2 of the '571 patent. It is thus seen that the combination of these three patents fails to show or suggest a rigid release liner to which the electrodes are sealed to provide moisture barrier enclosures for the gel of both electrodes. For desiccation prevention purposes Olson et al. and their '571 patent use the familiar envelope or pouch. For these reasons it is respectfully submitted that the combination of Walters, Keusch et al. and the Olson et al. patents cannot render Claim 9 unpatentable. Its dependent Claims 10-17 are patentable over the same patents by reason of their dependency.

To complete the citations for this application, the above-referenced '385 patent to Bishay et al. and the Olson et al. '571 patent are enclosed in an information disclosure statement. Also enclosed is US Pat. 3,961,623 to Milani et al. which, similar to Heath, has an aluminum foil cover 50 adhesively attached over the gel pad 46 of their electrode. US Pat. 6,694,193 to Lyster et al. shows electrodes attached by their gel to opposite sides of a release liner made of paper or a polymer. There is no sealing of the electrodes to the release liner. Finally, US Pat. 4,034,854 (Bevilacqua) shows an assembly with electrodes mounted on a carrier member 14, shown twisted in Fig. 2, which is stored in a sealed envelope 12 to prolong the shelf life of the assembly.

In view of the foregoing amendment and remarks, it is respectfully submitted that Claims 1-3, 7, 18, 20 and 23 are not anticipated by Walters, that Claims 4, 5, and 21 are patentable over Walters and Keusch et al., that Claims 6 and 19 are patentable over Walters and Heath, and that Claims 9-16 are patentable over Walters, Keusch et al. and Olson et al. Accordingly it is respectfully requested that the rejection of Claims 1-3, 7, 18, 20 and 23 under 35 U.S.C. §102(b) and of Claims 4-6, 9-16, and 18-21 be withdrawn.

In light of the foregoing amendment and remarks, it is respectfully submitted that this application is now in condition for allowance. Favorable reconsideration is respectfully requested.

Respectfully submitted,

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